IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
MCALLEN DIVISION

PETRA ROJAS, Plaintiff, v. WYETH, LLC, *et al.*, Defendants.	CIVIL ACTION NO. 7:12-cv-00193 JUDGE MICAELA ALVAREZ

DEFENDANTS ACTAVIS ELIZABETH LLC AND TEVA PHARMACEUTICALS USA, INC.'S REPLY IN SUPPORT OF THE MOTION TO DISMISS

Defendants Actavis Elizabeth LLC, individually and as successor in interest to Purepac Pharmaceutical Co. (erroneously identified as Purepac Pharmaceuticals), and Teva Pharmaceuticals USA, Inc. (hereinafter collectively referred to as "Generic Defendants"), by and through counsel, respectfully submit this reply brief in support of their motion to dismiss.

1. In her response to the motion to dismiss, Plaintiff argues that there are many non-warning claims in her Petition. Generic Defendants call the attention of the Court to *Centocor, Inc. v. Hamilton*, 372 S.W. 3d 140, 168-69 (Tex. 2012). This decision by the Supreme Court of Texas, rendered after this Court's decision in *Eckhardt v. Qualitest Pharm. Inc.*, ___ F. Supp. 2d. ___, No. 7:11-cv-00235, 2012 WL 1511817 (S.D. Tex. Apr. 30, 2012), confirms that in Texas claims against pharmaceutical companies based on alleged inadequacies in a product label, no matter how they are titled, are failure-to-warn claims. In *Centocor*, the plaintiffs alleged injuries from a

prescription drug and originally asserted causes of action for strict liability (failure to warn), negligence, gross negligence, fraud, and malice. At trial, attempting to avoid application of the learned intermediary doctrine, plaintiffs sought to abandon the failure-to-warn claims and recast them as claims for negligent misbranding, negligent marketing, and misrepresentations to prescribing physicians. The Texas Supreme Court held that plaintiffs could not do so and that the crux of the complaint was a failure to provide an adequate warning. This confirms this Court's decision in *Eckhardt* that "this is primarily a failure to warn case." *Eckhardt, supra,* at *4.

2. Since this Court's decision in *Eckhardt* and the Brownsville Division of this Court's decision in *Del Valle v. Qualitest Pharm. Inc.*, No. 1:11-cv-00113, 2012 WL 2899406 (S.D. Tex. June 22, 2012), the Brownsville Division – in *Phares v. Actavis-Elizabeth LLC*, No. 1:11-CV-00063, 2012 WL 1511817 (S.D. Tex. Aug. 30, 2012) – and a Texas state court – in *Graham v. Pliva, Inc., et al*., Cause No. 2010-987-4, 170th District Court of McLennan County Texas (Oct. 5, 2012) – dismissed claims like Plaintiff's. The *Phares* opinion is attached as Exhibit 1 and the *Graham* dismissal (without opinion) is attached as Exhibit 2.

3. In Plaintiff's response to the motion to dismiss, she alleges an exception based on failure to update labels, but as in *Eckhardt* this claim was advanced for the first time in the response to the motion to dismiss and was not raised in the active complaint. On the merits, this claim is precluded by a federal statute – 21 U.S.C. § 337(a) which provides that proceedings for enforcement, or to restrain violations, of the federal Food, Drug, and Cosmetic Act ("FDCA") "shall be by and in the name of the United States." Relying on this statute, a number of courts have held that an alleged failure to comply

with the FDCA cannot form the basis of a state-law claim. *See, e.g.*, *Phelps v. Wyeth, Inc.*, 857 F. Supp. 2d 1114, 1126 (D. Or. 2012); *Jacobsen v. Wyeth, LLC*, No. 10-0823, 2012 WL 3575293 (E.D. La. Aug. 20, 2012); *Strayhorn v. Wyeth, Inc.*, --- F. Supp. 2d ---, 2012 WL 3261377 (W.D. Tenn. Aug. 8, 2012); *Bowman v. Wyeth, LLC*, No. 10-1946, 2012 WL 684116 (D. Minn. Mar. 2, 2012); *Gross v. Pfizer, Inc.*, No. 8:10-CV-0010, 2012 WL 273731 (D. Md. Jan. 27, 2012); *Del Valle v. PLIVA, Inc.*, No. 1:11-cv-00113, 2011 WL 7168620 (S.D. Tex. Dec. 21, 2011) adopted by *Del Valle v. Qualitest Pharm. Inc.*, 2012 WL 2899406 (S.D. Tex. June 22, 2012).

4. In her response, Plaintiff also alleges an exception to *Mensing* based on an alleged failure to communicate the label change to the doctor. Just as in *Eckhardt*, Plaintiff pled a contradictory theory in her Petition – that the warning *was* communicated. Further, numerous courts post-*Mensing* have found this claim to be preempted. *See, e.g.*, *Smith v. Wyeth*, 657 F.3d 420, 423 (6th Cir. 2011) (finding preemption despite plaintiffs' argument that "Mensing does not preempt state tort liability for failing to communicate this FDA-approved warning to Appellants' prescribers."); *Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011) (the Eighth Circuit refused to permit supplemental briefing on this issue after the Supreme Court's decision); *Brinkley v. Pfizer, Inc.*, No. 10-0274-CV, 2012 WL 1564945 at *5 (W.D. Mo. Apr. 12, 2012) (The court said that there was "no state law requiring [the generic drug manufacturer] to communicate [the FDA-approved] warning" to physicians, and that it was "readily apparent that plaintiff is simply trying to backdoor claims against [the generic drug manufacturer] that the Supreme Court have found to be preempted.")

5. Plaintiff also asserts for the first time in her response that Generic Defendants engaged in off-label promotion and marketing of metoclopramide in violation of federal regulations. Yet Plaintiff's Petition offers absolutely no well-pleaded facts to support this naked allegation in her response. The baseless misrepresentation claims in the Petition do not support Plaintiff's new off-label promotion argument because these claims do not meet the Rule 8(a) standards articulated in *Bell Atl. Corp. v. Twombly*, requiring Plaintiff to plead allegations that "raise a right to relief above the speculative level." 550 U.S. 544, 555 (2007). Furthermore, only the federal government may bring an action for violations of the FDCA. *See* 21 U.S.C. § 337(a) (providing that proceedings for enforcement, or to restrain violations, of FDCA "shall be by and in the name of the United States"). Any attempt privately to enforce those provisions is not permitted. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (stating "FDCA leaves no doubt that it is the federal government rather than private litigants who are authorized to file suit for noncompliance" of its provisions). Accordingly, Plaintiff cannot bring these claims.

6. Plaintiff cites *Bartlett v. Mutual Pharmaceutical Company,* 678 F.3d 30 (1st Cir. 2012) as authority on two separate issues – that a design defect claim is not preempted and that preemption is also avoided by a failure to suspend sales. This is unavailing for several reasons.

7. First, Plaintiff did not allege a design defect claim in her Petition which would pass muster under *Twombly* and *Iqbal*. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, 'to state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009) (quoting

Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.' ... Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.' " *Id.* at 678 (quoting *Bell Atl. Corp.,* 550 U.S. at 555, 557). While Plaintiff's Petition contains conclusory, vague allegations to design defect, only boilerplate language is used and there are no facts set forth to support them so the design defect claim is subject to dismissal on that ground alone. It should also be noted that the only possible alleged design defect plaintiffs in the metoclopramide litigation can point to is an alleged defect in the "packaging" (i.e., the labeling in the package insert), which is a claim subject to dismissal under *Mensing*, as numerous courts have so held. *Jacobsen v. Wyeth, LLC*, No. 10–0823, 2012 WL 3575293, at *10 (E.D. La. Aug. 20, 2012) (The court found that plaintiff's design defect claim, which concerned packaging rather than the design of the drug, "sounds in failure to warn and is preempted under *Mensing.*"); *Cooper v. Wyeth, Inc.,* Civ. Act. No. 09–929, 2012 WL 733846, at *9 (M.D. La. March 6, 2012) ("Plaintiffs assert that defendants' products were unreasonably dangerous in design for failing to incorporate design changes 'such as packaging designs intended to mitigate the risk posed by long-term use.' ... The Court finds it is merely a failure-to-warn claim that has been worded to appear otherwise...."); *Fullington v. PLIVA, Inc.,* No. 4:10CV00236, 2012 WL 1893749, at *4 -5 (E.D. Ark. May 23, 2012) ("That her allegation of a design defect, in substance, is a claim of inadequate warning dovetails with the rest of Fullington's claims throughout her complaint, all of which revolve around accusations that the metoclopramide manufacturers failed to warn consumers of the dangers of the drug. Thus, this allegation is also an inadequate warning claim and not a

true design defect claim. Fullington has failed to allege a design defect claim.")

8. Second, to the extent that this would be viewed as a classic design defect claim, it is preempted under the rationale of *Mensing* because just as the labeling for generics must be the same as the brand name, so must the ingredients themselves. The sameness requirement which led to preemption of labeling under *Mensing* leads to preemption of any true claim of design defect under the same sameness principles. 21 U.S.C. § 355(j)(2)(A)(ii), (iii); *see also Mensing*, 131 S. Ct. at 2574 n.2 ("'[G]eneric drug' refers to a drug designed to be a copy of a reference listed drug (typically a brand-name drug), and thus identical in active ingredients, safety, and efficacy."). Any state-law requirement that generic metoclopramide be designed differently from brand-name Reglan® would, therefore, directly conflict with federal law. *See, e.g., In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, MDL No. 2226, 2012 WL 716132, at *3 (E.D. Ky. Mar. 5, 2012), app. pending (finding preempted any claim "based on the allegedly defective design of the drug, which the Generic Defendants, bound by their 'ongoing federal duty of sameness,' were powerless to change") (*citing Mensing*); *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, 484 (E.D.N.Y. Jan. 30, 2012) ("In *Mensing*, the Supreme Court found that a generic drug is 'designed to be a copy of a reference listed drug (typically a brand-name drug)' and it must be 'identical in active ingredients, safety, and efficacy.' Thus, the 'federal duty of sameness,' also applies in the context of generic drug design, and federal law preempts state laws imposing a duty to change a drug's design on generic drug manufacturers.") (citing *Mensing*); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, MDL. No. 2243, 2011 WL 5903623, at *6 (D.N.J. Nov. 21, 2011); *Stevens v. PLIVA, Inc.*, No. 6:10-0886, 2011 WL 6224569, at

*2 (W.D. La. Nov. 15, 2011).

9. Third, *Bartlett* also suggests that there is no impossibility preemption because the manufacturers could have withdrawn the product from the market. In that regard, it clearly runs contrary to the consensus of other federal courts. Most notably, it runs contrary to the Supreme Court's denial of rehearing based solely upon this one argument. *See Pliva v. Mensing,* 132 S. Ct. 55, 2011 WL 2874547, at *1-3 (July 18, 2011) (denying petition for rehearing). And as noted by the Eastern District of Kentucky, which specifically commented upon *Bartlett's* adoption of this argument:

> This argument—which failed to persuade either the Supreme Court or the Eighth Circuit on remand in *Mensing*, and the Sixth Circuit in *Smith v. Wyeth, Inc.*—is no more availing now. Moreover, the First Circuit offered little explanation for accepting it, noting simply that the *Mensing* opinion had not specifically addressed design-defect claims.

In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig., MDL No. 2226, 2012 WL 2457825, at *1 (E.D. Ky. June 22, 2012) (citation omitted). *See also*, *Phelps v. Wyeth, Inc. et al*, No. 6:09-cv-06168, Doc. No. 333 (D. Or. Sept. 28, 2012) (finding *Bartlett* does not compel reconsideration) (Attached as Exhibit 3).

10. It should be noted that in *Bartlett* there is currently pending a Petition for Certiorari in the Supreme Court. That Petition was filed in no large measure because the First Circuit itself acknowledged that "(t)o refuse preemption here is . . . in tension" with the rationale of *Mensing*. *Bartlett, supra,* at 38.

11. Moreover, *Bartlett* is distinguishable on its own terms. The *Bartlett* plaintiff argued that the generic drug at issue (sulindac) was unreasonably dangerous at all times and for all uses. *Bartlett*, 678 F.3d at 34-35. Here, by contrast, Plaintiff suggests only that metoclopramide is defectively designed due to inadequate warnings – a

different point from the one addressed in *Bartlett*. *See Strayhorn v. Wyeth, Inc.*, --- F. Supp. 2d ---, 2012 WL 3261377, at *10 (W.D. Tenn. Aug. 8, 2012) (finding "*Bartlett* does not squarely apply" because "it involved a drug which the plaintiff alleged was unreasonably dangerous; here, the crux of Plaintiffs' unreasonably dangerous argument is that metoclopramide is unreasonably dangerous when taken for more than twelve weeks"); *Fullington v. PLIVA, Inc.*, No. 10-cv-236, 2012 WL 1893749, at *5 (E.D. Ark. May 23, 2012), app. pending (explaining that "*Bartlett* is not on point" because "the core theory was that the risks of the generic drug sulindac outweighed its benefits" in all cases, whereas plaintiff "concede[d] that metoclopramide is not unreasonably dangerous if used properly").

12. Plaintiff cites a California Superior Court decision, *In re Reglan/Metoclopramide Cases*, No. CJC-10-004631 (Cal. Sup. Ct. Apr. 17, 2012), but it has been specifically rejected by federal courts. *See Strayhorn*, *supra* at 10 ("Plaintiffs' reliance on a California Superior Court decision does not persuade the Court: not only is the California decision in the vast minority of the courts to look at the issue, the Court does not find the California court's reasoning compelling.")

13. Plaintiff also cites an order from a state court in Philadelphia. *In re Reglan/Metoclopramide Litigation*, No. 1997 (Phila. Ct. Comm. Pleas Nov. 18, 2011). But the court did not address the merits of the preemption issue; it simply deferred ruling on them until the summary judgment stage. Defendants' appeal from that ruling will be heard on October 31, 2012.

CONCLUSION

For all the foregoing reasons, Generic Defendants' Motion to Dismiss should be granted.

Respectfully submitted,

By: *s/ Michael A. Logan*
Michael A. Logan
Attorney-In-Charge
State Bar No. 12497500
S.D. Bar No. 177828
E-mail: mlogan@krcl.com
Jennifer L. Cloud
State Bar No. 24046296
S.D. Bar No. 38017
E-mail: jcloud@krcl.com

KANE RUSSELL COLEMAN & LOGAN PC
3700 Thanksgiving Tower
1601 Elm Street
Dallas, Texas 75201
Tel: (214) 777-4294
Fax: (214) 777-4299

OF COUNSEL:
Julie A. Callsen
E-Mail: julie.callsen@tuckerellis.com

TUCKER ELLIS & WEST, LLP
925 Euclid Avenue, Suite 1150
Cleveland, OH 44115-1414
Tel: (216) 592-5000
Fax: (216) 592-5009

ATTORNEYS FOR DEFENDANT ACTAVIS ELIZABETH LLC

By: *s/ Michael A. Walsh*
Michael A. Walsh
Texas State Bar No. 00790146
SD Texas Bar No. 21846
STRASBURGER & PRICE, LLP
901 Main Street, Suite 4300
Dallas, TX 75202
Phone: 214-651-4300
Fax: 214-651-4330
E-mail: michael.walsh@strasburger.com

Jonathan I. Price Esq.
Nilda M. Tulla-Isidro, Esq.
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, New York 10018
Phone: 212-813-8800
Fax: 212-355-3333
E-mail: JPrice@goodwinprocter.com
E-mail: NTulla@goodwinprocter.com

Richard A. Oetheimer, Esq.
GOODWIN PROCTER LLP
Exchange Place
53 State Street
Boston, MA 02109
Phone: 617-570-1000
Fax: 617-523-1231
E-mail: ROetheimer@goodwinprocter.com

ATTORNEYS FOR DEFENDANT TEVA PHARMACEUTICALS USA, INC.

CERTIFICATE OF SERVICE

I hereby certify that on October 17, 2012, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic system. Parties may access this filing through the Court's system.

/s/ Michael A. Logan